DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2015

SpineCraft, LLC
Ms. Ami Akallal-Asaad
Vice President, Regulatory Affairs & Quality Assurance
777 Oakmont Lane
Westmont, Illinois 60559

Re: K143683
Trade/Device Name: APEX-DL Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP
Dated: April 20, 2015
Received: April 24, 2015

Dear Ms. Akallal-Asaad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143683

Device Name

APEX-DL SPINE SYSTEM

Indications for Use *(Describe)*

The APEX-DL Spine System with APEX Spine System Components is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

The APEX-DL Spine System with APEX Spine System Components is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 to S1), and for whom the device is intended to be removed after solid fusion is attained.

The APEX-DL Spine System with APEX Spine System Components is also a sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

When used in a percutaneous posterior approach with AIM MIS instrumentation, the APEX-DL Spine System with APEX Spine System Components is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the APEX-DL Spine System implants with APEX Spine System Components are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The APEX DL Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

*5*10(k) Summary

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) Summary is submitted for the APEX-DL Spine System.

Date Prepared: April 20, 2015

1. **Submitter:**

SpineCraft, LLC
777 Oakmont Lane
Westmont, IL 60559 USA
Tel: (630) 920-7300
Fax: (630) 920-7310

Contact Person:

Ami Akallal-Asaad
VP, Regulatory Affairs & QA
SpineCraft, LLC
a.asaad@spinecraft.com

2. **Trade name:** APEX-DL Spine System
   Common Name: Pedicle Screw Spine System

Classification Product Code:	Pedicle screw spinal system per NKB 888.3070 Class III
Subsequent Product Codes:	Pedicle screw spinal system, adolescent idiopathic scoliosis per OSH 888.3070
	Pedicle screw spinal system per MNI 888.3070
	Pedicle screw spinal system per MNH 888.3070
	Spinal interlaminal fixation orthosis per KWP 888.3050

3. **Primary predicate or legally marketed device which is substantially equivalent:**

- EXPEDIUM Verse Spine System (K142185) DePuy Synthes Spine

4. **Secondary predicate devices:**

- Viper Spine System (K090648 / K102701) DePuy Spine
- APEX Spine System (K062513 / K092825 / K102488 / K110906 / K132603) SpineCraft
- Xia Spinal System (K113666 / K071373 / K060748) Stryker
- SPINE-TECH SILHOUETTE SPINAL FIXATION SYSTEM (K980288) SPINE-TECH, INC
- MOSS MIAMI SS (K950697 / K000536) DePuy Spine
- Synergy VLS – open – (K940631 / K950099) Cross Medical
- Ti Expedium 4.5 Spine System (K081252) DePuy Spine

5. **Description of the device:**

The APEX-DL Spine System includes Monoaxial, Uniplanar, and Polyaxial Double Lead Thread Screws in the cannulated and non-cannulated versions and in regular and reduction (extended tab) versions. APEX-DL Spine System is a low profile thoracolumbar implant for use with wide range of patient statures. The APEX-DL Spine System Polyaxial screws feature a friction head, which is designed to provide precise reduction mechanism as a result of easier rod capturing. The APEX-DL Spine System also includes Lordosed Percutaneous Rods. The APEX-DL Spine System is compatible with the APEX Spine System 5.5mm and 6.0mm rods, hooks, side-by-side connectors, iliac connectors, cross connectors, and washers.

6. **Material:**

Titanium alloy (Ti-6Al-4V ELI) per ASTM F136
Cobalt chromium alloy (Co-28Cr-6Mo) per ASTM F1537

7. Substantial equivalence claimed to predicate devices:

APEX-DL Spine System is substantially equivalent to the predicate devices identified above in terms of intended use, design (fundamental scientific technology), materials, mechanical safety and/or performance, sterility, and biocompatibility.

8. Intended Use:

The APEX-DL Spine System with APEX Spine System Components is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

The APEX-DL Spine System with APEX Spine System Components is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 to S1), and for whom the device is intended to be removed after solid fusion is attained.

The APEX-DL Spine System with APEX Spine System Components is also a sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

When used in a percutaneous posterior approach with AIM MIS instrumentation, the APEX-DL Spine System with APEX Spine System Components is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the APEX-DL Spine System implants with APEX Spine System Components are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The APEX DL Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

9. Non-clinical Test Summary:

The following tests were conducted:

- ASTM F1717, “Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model”. Testing included Static Compression Bending Tests, Static Torsion Tests and Dynamic Compression Bending Tests.
- ASTM F1798 “Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies used in Spinal Arthrodesis Implants”. Testing included, Static Axial Gripping Capacity, Axial Torque Gripping Capacity, Static Flexion-Extension, and Dynamic Flexion-Extension.

The results of this testing were compared to predicate systems, with the results being equal or higher than the predicate systems.

10. Clinical Test Summary

No clinical studies were performed

11. Conclusions Nonclinical and Clinical

The APEX-DL Spine System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance, and function.